

Application No.: 10/074,272

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REMARKS

Claims 54, 55, 62-78, 80, 81, 83-91, 93-104, 106, 108-112, 114, 116, 117 and 119 are currently pending in this application. Claims 92, 105, 107, 113, 115 and 118 are cancelled. Claims 91, 101, 104, 106, 108, 110-112, 114, 116, 117 and 119 are amended herein. The amendments are supported by disclosure appearing in at least the following paragraphs: [0014], [0024], [0039]-[0044], [0105] and [0147]. Applicants respectfully request reconsideration in view of the above amendments and the following remarks.

Applicants would like to thank Examiner Chan for the personal interview with Applicant's representative on October 25, 2005. During the interview, Applicants' representative and the Examiner discussed the implications involved in making edible films, particularly edible films for the pharmaceutical industry. In particular, a predominant concern discussed at the interview was the importance of creating and maintaining compositional uniformity during the process of making the films, such that the compositional uniformity remained in the final film products. Compositional uniformity involves the overall uniform distribution of components throughout the film, and obviously has complexities well beyond the physical appearance of the film. This complexity was explained at the interview. Compositional uniformity is particularly necessary when actives, such as pharmaceutical actives are incorporated into the film. The inventive process creates and maintains compositional uniformity throughout the film, which allows the film product to be divided into numerous individual dosage units that contain the same amount of active per unit. Such uniformity is vital to pharmaceutical manufacturing, which involves concerns such as uniform dosing and FDA approval processes. For example, the amount of active in a given dosage unit must be controlled in order to be legally sold. In cases of prescription actives, the FDA approval requirements are very strict with respect to ensuring that the public receives the proper dose of the active. The difficulties of forming a commercially viable edible film, on a manufacturing scale, which contains a uniform distribution of components, was discussed at the interview.

As further discussed during the interview, the prior art does not address compositional uniformity nor processes for achieving such uniformity in films. In that regard, several process recitations were discussed to further clarify Applicants' process of forming edible films having compositional uniformity throughout. As summarized in the Examiner's Interview Summary, the following potential claim amendments were discussed: (1) deaerating the polymer matrix by slow mixing; and (2) forming a visco-elastic film without aggregates or conglomerates thereby maintaining the compositional uniform distribution of components in the edible film. As further indicated in the Interview Summary, the Examiner agreed that such recitations were not disclosed or suggested in the art of record.

In view thereof, Applicants have amended all of the independent claims herein to contain a deaeration step, either by slow mixing or a variation thereof, and the second process recitation cited above, i.e., forming a visco-elastic film without aggregates or conglomerates thereby maintaining the compositional uniform distribution of components in the edible film.

Aggregates or conglomerates can include any form of aggregation or conglomeration in the film, such as aggregates or conglomerates of particulate matter or liquid or flowable matter. These amendments will be addressed in greater detail below.

Applicants' Response to Objection to the Drawings

The Examiner objects to the drawings under 37 C.F.R. §1.84(p)(5) because they allegedly include a reference character not mentioned in the description. More specifically, the Examiner asserts that the drawings include reference character "40" labeling an application roller, which is not mentioned in the description. Applicants have amended paragraph [0044] of the specification herein to identify the application roller by reference character "40". Accordingly, Applicants respectfully submit that the objection to the drawings has been obviated.

Applicants' Response to Double Patenting Rejection

Claim 119 is rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 1 of co-pending Application No. 10/768,809. Because

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Application No. 10/768,809 is currently pending, this is a provisional double patenting rejection. Once one of the two respective co-pending applications is in allowable form, Applicants will consider filing a terminal disclaimer, or canceling/amending claims, as necessary. Applicants request the issuance of an *Ex parte Quayle* action if this case is in all other respects found allowable.

Applicants' Response to Rejection under 35 U.S.C. §102 over Magoon

Claim 119 is rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,631,837 to Magoon (hereinafter “Magoon”). Applicants respectfully request reconsideration on the basis that Magoon fails to disclose each and every element of Applicants’ claim 119, as amended herein.

The Examiner asserts that Magoon discloses a method of forming fruit leather. According to the Examiner, the method:

includes providing a fruit pulp puree . . . which inherently includes water soluble polymer component such as dietary fiber or polysaccharides and a polar solvent such as fruit juice/water, applying the puree onto a polyester sheet on hot water, which heat the puree from the bottom up and dries the puree

(Office Action, at 4).

Applicants have amended claim 119 herein to further define the invention. In particular, Applicants have added the two clarifying recitations discussed during the interview with the Examiner and noted above, i.e., (1) deaerating the matrix by slow mixing and (2) forming a visco-elastic film without aggregates or conglomerates thereby maintaining the compositional uniform distribution of components in the film. Nowhere in Magoon are processes for forming compositionally uniform films, particularly including these two additional steps disclosed or suggested. Magoon merely teaches drying fruit leather, and thus, is not concerned with uniform distribution of components. Therefore, Magoon fails to anticipate claim 119, as amended herein.

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In view thereof, it is respectfully submitted that claim 119 is patentable over Magoon.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush

Claims 91-93, 97, 100, 101, 104-109, 111-115 and 117-119 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 6,660,292 to Zerbe et al. (hereinafter "Zerbe") in view of U.S. Patent No. 5,881,476 to Strobush et al. (hereinafter "Strobush"). Applicants respectfully request reconsideration on the basis that the combination of references fails to render the claims obvious, as amended herein.

The Examiner asserts that Zerbe discloses a method of forming flavored film. Zerbe, however, teaches nothing more than generally drying the film. Zerbe contains no disclosure regarding the formation of a compositionally uniform film, nor the process steps for achieving such film. Compositional uniformity is not even recognized as a concern in Zerbe.

Meanwhile, the Examiner cites Strobush, a patent directed to application of aesthetic coatings (mottle-free) on photographs. Strobush is cited for its alleged disclosure of applying hot air to the bottom of a surface to dry the coating. Strobush is not concerned with maintaining uniformity of the coating composition, but rather merely the appearance of the coating. Moreover, photographic coatings are distinctly different from edible, self-supporting films containing actives. Accordingly, one of ordinary skill in the pharmaceutical art would not be motivated to look to Strobush for teachings of relevance to the preparation of edible films. Due to their disparate subject matter, therefore, Zerbe and Strobush are not properly combinable in forming an obviousness rejection against Applicants' claims.

Even if Zerbe and Strobush were properly combinable, however, the references fail to disclose or suggest Applicants' combination of process steps for forming an edible film having compositional uniformity. Furthermore, as mentioned above, Applicants have amended independent claims 91, 101, 104, 106, 108, 111, 112, 114, 117 and 119 herein to further clarify

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the claimed process, which creates and maintains compositional uniformity. In particular, Applicants have amended the claims to require two additional process steps, as discussed during the interview and noted above.

Claims 91, 106, 111, 114, 117 and 119 are amended herein to recite the following two steps: (1) deaerating the matrix by slow mixing and (2) forming a visco-elastic film without aggregates or conglomerates thereby maintaining the compositional uniform distribution of components in the film.

Claims 101, 104, 108 and 112 are amended herein to recite a deaeration step involving a variant of controlled or slow mixing and the second process step specifically recited above, i.e., forming a visco-elastic film without aggregates or conglomerates thereby maintaining the compositional uniform distribution of components in the film.

Nowhere in Zerbe or Strobush is Applicants' combination of process steps to form a compositionally uniform film disclosed or suggested, particularly including the two additional steps added herein. Therefore, the cited combination fails to render claims 91, 101, 104, 106, 108, 111, 112, 114, 117 and 119, and those claims that depend therefrom, obvious, as amended herein.

In addition to the incorporation of the two process steps discussed above, Applicants also have amended claims 104, 106, 110 and 117 to further define each embodiment. More specifically, Applicants have amended claim 104 to further define the active component as a pharmaceutical active and/or a cosmetic active. Applicants have amended claim 106 to further require formation of the wet film "within a time period before the active degrades." Applicants have amended claim 110 to further define the active component as a pharmaceutical active. Applicants have amended claim 117 to require specific premixing and mixing steps disclosed in paragraphs [0043]-[0044] of the specification, as originally filed. Zerbe and Strobush also fail to

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teach or suggest each of these recitations, and thus, fail to render amended claims 104, 106, 110 and 117 obvious for these additional reasons.

In view of the above, it is respectfully submitted that claims 91, 101, 104, 106, 108, 111, 112, 114, 117 and 119, and claims 93, 97, 100 and 109, which depend therefrom, are patentable over Zerbe and Strobush, each taken alone or in combination.

Applicants' Response to Rejections under 35 U.S.C. §103 over Zerbe in view of Strobush and Horstmann

Claims 94, 95 and 110 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush and U.S. Patent No. 5,629,003 to Horstmann et al. (hereinafter "Horstmann"). Applicants respectfully request reconsideration on the basis that the combination of references fails to render the claims obvious, as amended herein.

Claims 94 and 95 depend from claim 91, and thus, require all of the limitations of claim 91, as amended herein. As discussed in detail above with regard to claim 91, Zerbe and Strobush fail to disclose, teach or suggest Applicants' process of forming compositionally uniform films, particularly including the process steps added to claim 91, i.e., (1) deaerating the matrix by slow mixing and (2) forming a visco-elastic film without aggregates or conglomerates thereby maintaining the compositional uniform distribution of components in the film. Independent claim 110 has been amended similar to claim 91. The combination of Zerbe and Strobush, therefore, also fails to teach or suggest amended claim 110.

Moreover, Henderson was cited merely for its disclosure relating to film thickness. Henderson contains no disclosure of relevance to Applicants' process of forming edible films having compositional uniformity, nor the additional process steps recited in amended claims 91 and 101. Therefore, Henderson fails to cure the deficiencies of Zerbe and Strobush in this regard.

Accordingly, Zerbe, Strobush and Henderson, each taken alone or in combination, fail to render claims 94, 95 and 110 obvious. It is respectfully submitted that claims 94, 95 and 110 are patentable over such combination of art.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush and Wittwer

Claim 96 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush and U.S. Patent No. 4,478,658 to Wittwer (hereinafter "Wittwer"). Applicants respectfully request reconsideration on the basis that the combination of references fails to render the claim obvious, as amended herein.

Claim 96 depends from claim 91, and thus, requires all of the limitations of claim 91, as amended herein. As discussed in detail above with regard to claim 91, Zerbe and Strobush fail to disclose, teach or suggest Applicants' process of forming compositionally uniform films, particularly including the process steps added to claim 91. Wittwer was cited merely for its disclosure relating to film viscosity. Wittwer contains no disclosure of relevance to Applicants' process as recited in amended claim 91. Therefore, Wittwer fails to cure the deficiencies of Zerbe and Strobush in this regard.

As such, Zerbe, Strobush and Wittwer, each taken alone or in combination, fail to render claim 96 obvious. It is respectfully submitted that claim 96 is patentable over the cited combination.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush and Zerbe '957

Claims 98, 99, 102 and 103 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush and U.S. Patent No. 6,231,957 to Zerbe et al. (hereinafter "Zerbe '957"). Applicants respectfully request reconsideration on the basis that the combination of references fails to render the claims obvious, as amended herein.

Claims 98 and 99 depend from claim 91, and thus, require all of the limitations of claim 91, as amended herein. Claims 102 and 103 depend from claim 101, and thus, require all of the limitations of claim 101, as amended herein. Again, as discussed in detail above with regard to claims 91 and 101, Zerbe and Strobush fail to teach or suggest Applicants' process of forming compositionally uniform films. Moreover, Zerbe '957 was cited merely for its disclosure relating to cutting film into pieces and packaging the films into containers. Zerbe '957 contains no disclosure of relevance to edible films having compositional uniformity, nor processes for achieving such films. Zerbe '957, therefore, fails to cure the deficiencies of Zerbe and Strobush in this regard.

As such, Zerbe, Strobush and Zerbe '957, each taken alone or in combination, fail to render claims 98, 99, 102 and 103 obvious. It is respectfully submitted that claims 98, 99, 102 and 103 are patentable over the cited combination.

Applicants' Response to Rejection under 35 U.S.C. §103 over Zerbe in view of Strobush and Mehra

Claim 116 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Zerbe in view of Strobush and U.S. Patent No. 5,733,575 to Mehra et al. (hereinafter "Mehra"). Applicants respectfully request reconsideration on the basis that the combination of references fails to render the claim obvious, as amended herein.

As in independent claim 91, Applicants have amended claim 116 herein to require two clarifying process steps, i.e., (1) deaerating the matrix by slow mixing and (2) forming a viscoelastic film without aggregates or conglomerates thereby maintaining the compositional uniform distribution of components in the film. As discussed in detail above, Zerbe and Strobush do not disclose or suggest Applicants' claimed process, particularly including these clarifying process steps.

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Moreover, Mehra was cited merely for its disclosure of anti-foaming agents and fails to include any disclosure of relevance to such process steps. Mehra, therefore, fails to cure the deficiencies of Zerbe and Strobush in this regard. As such, amended claim 116 is not obvious in view of Zerbe in combination with Strobush and Mehra.

In view thereof, it is respectfully submitted that amended claim 116 is patentable over Zerbe, Strobush and Mehra, each taken alone or in combination.

As such, claims 91, 93-104, 106, 108-112, 114, 116, 117 and 119 are believed to be in proper form for allowance. A favorable reconsideration of the application on the merits is earnestly solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,



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